4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Risks and Benefits of Hydroxyethyl Starch Solutions; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Risks and Benefits of Hydroxyethyl Starch Solutions." The purpose of this public workshop is to discuss new information on the risks and benefits of FDA-approved hydroxyethyl starch (HES) solutions.

The public workshop has been planned in partnership with the Department of Defense and the National Heart, Lung and Blood Institute, National Institutes of Health, and will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on September 6, 2012, from 8:00 a.m. to 5:30 p.m., and September 7, 2012, from 8:30 a.m. to 1:00 p.m.

Location: The public workshop will be held at the Masur Auditorium, National Institutes of Health, 10 Center Dr., Bldg. 10, Clinical Center, Bethesda, MD 20892.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, Phone: 301-827-6128, FAX: 301-827-2843, email: CBEROBRRWorkshops@fda.hhs.gov.

Registration: Mail, fax, or email your registration information (including name, title, firm or organization name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see Contact Person) by August 15, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:00 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

HES solutions are synthetic colloids administered intravenously to patients to maintain or expand plasma volume when clinically indicated. Currently, three such products are approved by FDA. HES solutions are indicated for the treatment of hypovolemia (low blood volume) that may result from trauma, sepsis, burns, or anaphylaxis. These products are used in the prehospital and hospital environment in both military and civilian settings. This public workshop will serve as a forum for discussing new information on the potential effects of HES solutions on hemostasis and on the renal system.

The first day of the public workshop will include presentations and panel discussions on the following topics: (1) The risks and benefits associated with HES solutions in different clinical settings and (2) the findings of two recent major clinical studies conducted on HES solutions.

The second day of the public workshop will include a summary discussion and presentations concerning the overall safety profile of HES solutions and a discussion of future clinical research for the evaluation of HES solutions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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